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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete If Known

Application Number	10/696,389
Filing Date	October 29, 2003
First Named Inventor	Lawrence T. Boni
Art Unit	1615
Examiner Name	Kishore, G. S.
Attorney Docket Number	TRA-008.01

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code* (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
AA*	US-4,451,447		05-29-1984	Kaplan et al.	
AB*	US-4,167,874		08-30-1988	Shimura et al.	
AC*	US-5,945,122		08-31-1999	Abra et al.	
AD*	US-5,665,383		09-09-1997	Grinstaff et al.	
AE*	US-6,090,407		07-18-2000	Knight et al.	
AF*	US-6,451,784-B1		09-17-2002	Placke et al.	
AG*	US-6,419,901-B2		07-16-2002	Placke et al.	
AH*	US-6,147,060		11-14-2000	Zasloff et al.	
AI*	US-6,440,393-B2		08-27-2002	Waldrep et al.	
AJ*	US-6,599,912		07-29-2003	Au et al.	
AK*	US-6,511,676		01-28-2003	Boulikas	
AL*	US-5,795,589		08-18-1998	Mayer et al.	
AM*	US-20020187105-A1		12-12-2002	Zou et al.	
AN*	US-5,049,389		09-17-1991	Radhakrishnan	
AO*	US-6,045,828		04-04-2000	Bystrom et al.	
AP*	US-5,875,776		03-02-1999	Vaghetti	
AQ*	US-5,006,343		04-09-1991	Benson et al.	
AR*	US-5,000,958		03-19-1991	Fountain et al.	
AS*	US-4,933,121		06-12-1990	Law et al.	
AT*	US-5,849,490		12-15-1998	Schonwetter et al.	
AU*	US-5,320,906		06-14-1994	Eley et al.	
AV*	US-6,352,996		03-05-2002	Cao et al.	
AW*	US-20030059375-A1		03-27-2003	Perez-Soler et al.	
AX*	US-5,459,127		10-17-1995	Felgner et al.	
AY*	US-4,372,949		02-08-1983	Kodama et al.	
AZ*	US-4,396,630		08-02-1983	Riedl et al.	
AA1*	US-4,394,448		07-19-1983	Szoka, Jr. et al.	
AB1*	US-5,178,876		01-12-1993	Khokhar et al.	
AC1*	US-5,334,761		08-02-1994	Gebeyehu et al.	
AD1*	US-4,693,999		09-15-1987	Axelson et al.	
AE1*	US-5,543,152		08-06-1996	Webb et al.	
AF1*	US-5,279,833		01-18-1994	Rose	
AG1*	US-5,264,618		11-23-1993	Felgner et al.	
AH1*	US-5,753,613		05-19-1998	Ansell et al.	
AI1*	US-4,895,719		01-23-1990	Radhakrishnan et al.	
AJ1*	US-5,077,056		12-31-1991	Bally et al.	
AK1*	US-5,741,516		04-21-1998	Webb et al.	
AL1*	US-5,049,388		09-17-1991	Jack V. Knight	
AM1*	US-5,616,334		04-01-1997	Janoff et al.	
AN1*	US-5,641,662		06-24-1997	Robert J. Debs	
AO1*	US-5,756,353		05-26-1998	Debs	
AP1*	US-6,843,942-A1		01-18-2005	Katinger et al.	
AQ1*	US-4,895,452		01-23-1990	Yiournas et al.	

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Sheet	2	of	5	Attorney Docket Number	TRA-008.01
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² -Number ³ -Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
BA	GB-2145107-A		03-20-1985			
BB	WO-86/06959		12-04-1986			
BC	WO-91/16882		11-14-1991			
BD	WO-96/19199		06-27-1996			
BE	WO-93/12240		06-24-1993			
BF	EP-0069307-A		01-12-1983		Abstract	
BG	WO-00/29103		05-25-2000			

*EXAMINER: Initial after reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied under 37 CFR 1.98(a)(2)(ii) because that application was filed after June 30, 2003 or is available in the IFW. *Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposia, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
CA	Nilven, Ralph et al., Nebulization of Liposomes. I. Effects of Lipid Composition, Report, pp. 1127-1133.		
CB	Katara, O.P., et al., Enhanced <i>in vivo</i> Performance of Liposomal Indomethacin Derived From Effervescent Granule Based Proliposomes, J. Microencapsulation, 1995, Vol. 12, No. 5, pp. 487-493.		
CC	Petkowicz, Jozefa, et al., Hypoglycemic Effect of Liposome-Entrapped Insulin Administered by Various Routes into Normal Rats, Pol. J. Pharmacol. Pharm., 1989, 41, pp. 299-304.		
CD	Comis, "Carboplatin in the Treatment of Non-Small Cell Lung Cancer: a Review," Oncology, 1993 Nov.; 50 (2): 37-41. (Abstract)		
CE	A.Bargoni, R. Cavalli, G.P. Zara, A. Fundaro, O. Caputo, M.R. Gasco (2001) Transmucosal transport of tobramycin incorporated in solid lipid nanoparticles (SLN) after duodenal administration to rats. Part I - Tissue distribution. Pharmacological Research 43(5): 497-502.		
CF	J. Lagace, M. Dubreuil, S. Montplaisir (1991) Liposome-encapsulated antibiotics: preparation, drug release and antimicrobial activity against <i>Pseudomonas aeruginosa</i> . Journal Microencapsulation 8(1): 53-61.		
CG	L.S. Ramsammy, G.J. Kaloyanides (1988) The effect of gentamicin on the biophysical properties of phosphatidic acid liposomes is influenced by the O-C=O group of the lipid. Biochemistry 27: 8249-8254.		
CH	C. Dees, R.D. Schultz (1990) The mechanism of enhanced intraphagocytic killing of bacteria by liposomes containing antibiotics. Veterinary Immunology and Immunopathology 24: 135-146.		
CI	J. Beaulac, S. Sachetelli, J. Lagace (1999) Aerolization of low phase transition temperature liposomal tobramycin as a dry powder in an animal model of chronic pulmonary infection caused by <i>Pseudomonas aeruginosa</i> . Journal Drug Targeting 7(1): 33-41.		
CJ	J.F. Marier, J.L. Brazier, J. Lavigne, M.P. Ducharme (2003) Liposomal tobramycin against pulmonary infections of <i>Pseudomonas aeruginosa</i> : a pharmacokinetic and efficacy study following single and multiple intratracheal administrations in rats. Journal Antimicrobial Chemotherapy 52: 247-252.		
Examiner Signature	/Gollamudi Kishore/	Date Considered	03/26/2008

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.K./

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(Use as many sheets as necessary)

Sheet	3	of	5	Attorney Docket Number	TRA-008.01
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CK	E.A. Poyner, H.O. Alpar, M.R.W. Brown (1993) Preparation, properties and the effects of free and liposomal tobramycin on siderophore production by <i>Pseudomonas aeruginosa</i> . <i>Journal Antimicrobial Chemotherapy</i> 34: 43-52.
CL	A. Omri, M. Ravaoarimoro, M. Poisson (1995) Incorporation, release and in vitro antibacterial activity of liposomal aminoglycosides against <i>Pseudomonas aeruginosa</i> . <i>Journal Antimicrobial Chemotherapy</i> 39: 631-639.
CM	C. Beaulac, S. Clement-Major, J. Hawari, J. Lagace (1997) In vitro kinetics of drug release and pulmonary retention of microencapsulated antibiotic in liposomal formulations in relation to the lipid composition. <i>Journal Microencapsulation</i> 14(3): 335-348.
CN	P. Demaeyer, E.M. Akodad, E. Gravet, P. Schietecat, J.P. van Vooren, A. Drowart, J.C. Yernault, F.J. Legros (1993) Disposition of liposomal gentamicin following intrabronchial administration in rabbits. <i>Journal Microencapsulation</i> 10(1): 77-88.
CO	M. Antos, E.A. Trafny, J. Grzybowski (1995) Antibacterial activity of liposomal amikacin against <i>Pseudomonas aeruginosa</i> in vitro. <i>Pharmacological Research</i> 32(1/2): 84-87.
CP	R.M. Schiffers, G. Storm, I.A.-J.M. Bakker-Woudenberg (2001) Therapeutic efficacy of liposomal gentamicin in clinically relevant rat models. <i>International Journal Pharmaceutics</i> 214: 103-105.
CQ	L.E. Bermudez, A.O. Yau-Young, J.-P. Lin, J. Cogger, L.S. Young (1999) Treatment of Disseminated <i>Mycobacterium avium</i> Complex Infection of Beige Mice with Liposome-Encapsulated Aminoglycosides. <i>Journal Infect. Dis.</i> 161: 1262-1268.
CR	J.H. Zhang and J.B. Zhu (1999) A Novel Method to Prepare Liposomes Containing Amikacin. <i>Journal Microencapsulation</i> 16(4): 511-516.
CS	S. Zeng, C. Hu, H. Wei, Y. Lu, Y. Zhang, J. Yang, G. Yun, W. Zou, B. Song (1993) Intravitreal Pharmacokinetics of Liposome-encapsulated Amikacin in a Rabbit Model. <i>Ophthalmology</i> 100: 1640-1644.
CT	M.H. Cynamon, C.E. Swenson, G.S. Palmer, & R.S. Ginsberg (1989) Liposome-Encapsulated-Amikacin Therapy of <i>Mycobacterium avium</i> Complex Infection in Geige Mice. <i>Antimicrobial Agents and Chemotherapy</i> 33(8): 1179-1183.
CU	R.M. Fielding, L. Moon-McDermott, R.O. Lewis, M.J. Horner (1999) Pharmacokinetics and Urinary Excretion of Amikacin in Low-Clearance Unilamellar Liposomes after a Single or Repeated Intravenous Administration in the Rhesus Monkey. <i>Antimicrobial Agents and Chemotherapy</i> 43(3): 503-509.
CV	K. Yanagihara (2002) Design of anti-bacterial drug and anti-Mycobacterial drug for drug delivery system. <i>Current Pharmaceutical Design</i> 8: 475-482.
CW	T.C. Whitehead, A.M. Lovering, L.M. Cropley, P. Wade, R.N. Davidson (1998) Kinetics and Toxicity of Liposomal and Conventional Amikacin in a Patient with Multidrug-Resistant Tuberculosis. <i>Eur J Clin Microbiol Infect Dis</i> 17: 794-797.
CX	E. A. Petersen, J.B. Grayson, E.M. Hersh, R.T. Dorr, S.-M. Chiang, M. Oka, R.T. Proffitt (1996) Liposomal amikacin: improved treatment of <i>Mycobacterium avium</i> complex infection in the beige mouse model. <i>Journal Antimicrobial Chemotherapy</i> 38: 819-828.
CY	A.A. Roehrborn, J.F. Hansbrrough, B. Gauldoni, S. Kim (1995) Lipid-based slow-release formulation of amikacin sulfate reduces foreign body associated infections in mice. <i>Antimicrobial Agents Chemotherapy</i> 39: 1752-1755.
CZ	S.B. Howell (2001) Clinical applications of a novel sustained-release injectable drug delivery system: Depofoam Technology. <i>Cancer Journal</i> 7: 219-227.
CA1	A. Omri & M. Ravaoarimoro (1996) Comparison of the Bactericidal Action of Amikacin, Netilmicin and Tobramycin in Free and Liposomal Formulation against <i>Pseudomonas aeruginosa</i> . <i>Chemotherapy</i> 42: 170-176.

Examiner Signature	/Gollamudi Kishore/	Date Considered	03/26/2008
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Sheet	4	of	5	Attorney Docket Number	TRA-008.01
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CB1	L. Kesavulu, J.A. Goldstein, R.J. Debs, N. Duzgunes, P.R.J. Gangadham (1990) Differential effects of free and liposome encapsulated amikacin on the survival of <i>Mycobacterium avium</i> complex in mouse peritoneal macrophages. <i>Tubercle</i> 71: 215-218.	
CC1	W.E. Bucke, S. Leitzke, J.E. Diederichs, K. Bonner, H. Hahn, S. Ehlers, and R.H. Muller (1997) Surface-Modified Amikacin-Liposomes: Organ Distribution and Interaction with Plasma Proteins. <i>Journal Drug Targeting</i> 5(2): 99-108.	
CD1	S. Ehlers, W. Bucke, S. Leitzke, L. Fortmann, D. Smith, H. Hansch, H. Hahn, G. Bancroft, and R. Muller (1996) Liposomal amikacin for treatment of <i>M. avium</i> infections in clinically relevant experimental settings. <i>Zbl. Bakt.</i> 284: 218-231.	
CE1	E.K. Kim and H.B. Kim (1990) Pharmacokinetics of intravascularly injected liposomes encapsulated tobramycin in normal rabbits. <i>Yonsei Medical Journal</i> 31(4): 308-314.	
CF1	A. Omri, C. Beauché, M. Bouhajib, S. Montplaisir, M. Sharkawi, J. Lagace (1994) Pulmonary retention of free and liposome-encapsulated tobramycin after intratracheal administration in uninjected rats and rats infected with <i>Pseudomonas aeruginosa</i> . <i>Antimicrobial Agents and Chemotherapy</i> 38(5) 1090-1095.	
CG1	J.R. Morgan and K.E. Williams (1980) Preparation and properties of liposome-associated gentamicin. <i>Antimicrobial Agents and Chemotherapy</i> 17(4) 544-548.	
CH1	P. Lutwyche, C. Cordeiro, D.J. Wiseman, M. St-Louis, M. Uh, M.J. Hope, M.S. Webb, B.B. Finlay (1998) Intracellular delivery and antibacterial activity of gentamicin encapsulated in pH-sensitive liposomes. <i>Antimicrobial Agents and Chemotherapy</i> 42(10) 2511-2520.	
CI1	R.M. Schiffrers, G. Storni, M.T.T. Kate, L.E.T. Stearne-Cullen, J.G. Den Hollander, H.A. Verbrugh, I.A.J.M. Bakker-Woudenberg (2001) In vivo synergistic interaction of liposome-encapsulated gentamicin and ceftazidime. <i>Journal Pharmacology Experimental Therapeutics</i> 298(1): 369-375.	
CJ1	A.I. Vitas, R. Diaz, and C. Gamazo (1996) Effect of composition and method of preparation of liposomes on their stability and interaction with murine monocytes infected with <i>Brucella abortus</i> . <i>Antimicrobial Agents and Chemotherapy</i> 40(1) 145-151.	
CK1	E.A. Trafny, M. Stepinak, M. Antos, J. Grzybowski (1995) Effects of free and liposome-encapsulated antibiotics on adherence of <i>Pseudomonas aeruginosa</i> to collagen type I. <i>Antimicrobial Agents and Chemotherapy</i> 39(12) 2645-2649.	
CL1	S.P. Klemens, M.H. Cynamon, C.E. Swenson, R.S. Ginsberg (1990) Liposome-encapsulated-gentamicin therapy of <i>Mycobacterium avium</i> complex infection in beige mice. <i>Antimicrobial Agents and Chemotherapy</i> 34(5) 967-970.	
CM1	S.D. Nightingale, S.L. Saleem, C.E. Swenson, A.J. Lawrence, D.A. Watson, F.G. Pilkiewicz, E.G. Silverman, S.X. Cal (1993) Liposome-encapsulated gentamicin treatment of <i>Mycobacterium avium</i> - <i>Mycobacterium</i> intracellular complex bacteremia in AIDS patients. <i>Antimicrobial Agents and Chemotherapy</i> 37(9) 1869-1872.	
CN1	C.E. Swenson, K.A. Stewart, J.L. Hammett, W.E. Fitzsimmons, R.S. Ginsberg (1990) Pharmacokinetics and in vivo activity of liposome-encapsulated gentamicin. <i>Antimicrobial Agents and Chemotherapy</i> 34(2) 235-240.	
CO1	I.A.J.M. Bakker-Woudenberg, M.T. ten Kate, L.E.T. Stearne-Cullen, M.C. Woodle (1995) Efficacy of gentamicin or ceftazidime entrapped in liposomes with prolonged blood circulation and enhanced localization in <i>Klebsiella pneumoniae</i> -infected lung tissue. <i>Journal Infectious Diseases</i> 171: 938-947.	
CP1	M.W. Fountain, S.J. Weiss, A.G. Fountain, A. Shen, R.P. Lenk (1985) Treatment of <i>Brucella canis</i> and <i>Brucella abortus</i> in vitro and in vivo by stable plurilamellar vesicle-encapsulated aminoglycosides. <i>Journal Infectious Diseases</i> 152(3): 529-535.	
CQ1	C.I. Price, J.W. Horton, C.R. Baxter (1992) Liposome delivery of aminoglycosides in burn wounds. <i>Surgery, Gynecology & Obstetrics</i> 174: 414-418.	

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				Art Unit	1615
				Examiner Name	Kishore, G. S.
				Attorney Docket Number	TRA-008.01

CR1	C.I. Price, J.W. Horton, C.R. Baxter (1994) Liposome encapsulation: a method for enhancing the effectiveness of local antibiotics. <i>Surgery</i> , 115(4): 480-4487.	
CS1	C.I. Price, J.W. Horton, C.R. Baxter (1989) Enhanced effectiveness of intraperitoneal antibiotics administered via liposomal carrier. <i>Arch Surgery</i> 124: 1411-1415.	

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